

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings includes changes to Figure 2. This sheet replaces the original sheet containing Figure 2. In Figure 2, reference numbers are changed to avoid using the same reference numbers used in Figure 1.

Attachments: Replacement Sheet for Figure 2; Annotated Sheet Showing Changes

REMARKS

Claims 9 and 16 are canceled without prejudice or disclaimer. Claims 1-18, 22 and 23 stand rejected. The specification is amended to reflect the renumbering of Figure 2 and to include elements of the processor as recited in the original claims in the description of the computer system. No new matter has been added.

Applicants respectfully thank the Examiner for indicating that claims 19-21, 24 and 25 are allowable if rewritten in independent form.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because of the use of the same reference numbers for elements of the subcombination and elements of the combination. Figure 2 is hereby amended to use new reference numbers. Therefore, the rejection is believed to be rendered moot with the submission of the replacement Figure 2.

The drawings are also objected to under 37 CFR 1.83(a). The Patent Office asserts that the drawings must show every feature of the invention specified in the claims. Applicants respectfully assert that the figures and figure description as amended comply with the requirement of Rule 1.83(a). Rule 83(a) recites that the drawings must show every feature of the claimed invention, “[h]owever, conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (e.g., a labeled rectangular box).”

Figure 1 shows a dispensing station, which is not currently claimed as a separate structure. Therefore, further details are not required in Figure 1. Figure 2 is an operational flow-chart showing a system for preparing individualized dosage forms. Claim 17 recites a system. The rectangular box labeled (7) in Figure 2 represents the central computer system in communication with the first, second and third databases and processor that are elements (a)-(d) of claim 17. The rectangular box labeled (10) in Figure 2 represents a mechanical transportation

system such as that recited in element (e) of claim 17. A series of dispensing stations is shown in Figure 2 as (11), such as is recited in step (f) of claim 17. The pellets and capsules referred to in claim 17, step (f) are shown in Figure 1 at numbers (4) and (5). Thus, the Figures comply with Rule 83(a) and reconsideration and withdrawal of the objection is requested.

Claim Rejections 35 USC § 112

Claims 9 and 16 are cancelled without prejudice or disclaimer. The rejection of these claims as being indefinite is rendered moot by the cancellation.

Claim Rejections – 35 USC § 103

The Patent Office rejects claims 1-5, 10-14, 17 and 22 as obvious over US Patent 4,712,511 (Zamzow) in view of US Patent 5,853,244 (Hoff). Applicants respectfully disagree.

Zamzow and Hoff are not analogous art to the present invention and should not be applied in an obviousness rejection. Zamzow and Hoff concern animal feed. Zamzow addresses a feed delivery system for individualized rations for cattle. Hoff concerns a system for accounting for microingredients used in animal feed. In contrast, the present invention concerns individualized dosage forms of pharmaceutical medicaments. The art of animal feed is remote from the pharmaceutical art. It is clearly not the same field of endeavor. Furthermore, the problems that the present inventor addresses are very different from the problems of Zamzow and Hoff. The present inventor addresses concerns about accurate administration of multiple medications with differing administration times and amounts. Another difficulty he addresses includes the inconvenience and discomfort of administering multiple tablets and capsules at dosaging time. Another problem is the accurate dosaging of medicaments to patients for whom the typical solid tablet is not easy to administer, such as children or the elderly who have swallowing problems. See specification, page 1, line 16 to page 5, line 2. These medical problems with administering small dosages of medicaments are not the same as the problems with cattle feed addressed in Zamzow and Hoff. The skilled person trying to address these issues with pharmaceutical dosaging would not look to methods of feeding animals. Therefore, the

cited references are not analogous art and reconsideration and withdrawal of the rejection is urged.

Additionally, Zamzow and Hoff do not teach certain elements of the present invention. Claims 1 and 17 and their dependent claims concern selecting pellets to form capsules. Zamzow and Hoff concern buckets of feed, not small pellets enclosed in a capsule. Claims 10 and 22 concern medicaments for reconstitution into a liquid and administration as a liquid. The Patent Office has not shown where this element is taught in either cited reference.

The present invention provides the option of selecting from two different packaging options depending on the dosing needs of the patient: capsules or a single container for liquid reconstitution. See, e.g., claims 1, 2, 3, 10, 11 and 12. The present claims are directed to proper ways for selecting and consolidating multiple packaging options - several capsules - for a single dosing interval. See, e.g., claims 4, 5, 6, 20 and 21. These elements are not taught in Zamzow or Hoff.

Claims 6-8 and 15 are rejected as obvious over Zamzow and Hoff. The Patent Office asserts that "pellets" need not be mentioned in the cited art yet the claimed invention can be found obvious. The reasoning asserted is that the article worked upon by a claimed apparatus may not be relied upon for patentability. Yet claims 6-8 and 15 are method claims, not apparatus claims. The law the Patent Office cites is inapplicable. It concerns patentability of apparatus or structure claims, and the present claims rejected are method claims. The pellets are used in multiple steps of the claimed methods to prepare an individualized dosage form. Therefore, the rejection is misplaced and should be withdrawn.

The pellets employed in the present application are specifically designed to meet the requirements and standards demanded of pharmaceutical products. The pellets are designed to prevent the interactions of the components and eliminate any detrimental physical-chemical interactions leading to instability of the medications, nutraceuticals and excipients during product storage. The pellets are also designed to erode specifically under aqueous conditions to allow for the appropriate physical-chemical and biological performance of the prepared products. The

invention would have no usefulness for pharmaceutical products without these specific formulations.

The invention teaches the use of specifically coated pellets with differentiated erosion under aqueous conditions. See, e.g., claims 6, 7, 8, and 10-15. The coatings allow for the medications and nutraceuticals to be isolated from each other and the excipients and thus provide stability during storage. Upon exposure to the aqueous environs of the stomach the coating erodes gradually allowing for the medication to be made available for therapeutic effects. Thus, the pellets and capsules are important for the invention and are not interchangeable with buckets of animal feed.

Conclusion

In view of the above, consideration and allowance are respectfully solicited.

In the event the Examiner believes an interview might serve in any way to advance the prosecution of this application, the undersigned is available at the telephone number noted below.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 07540-00005-USU from which the undersigned is authorized to draw.

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Respectfully submitted,



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